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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/674,185 | 09/29/2003 | William T. Donofrio | END 5032 | 1959 |

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EXAMINER

ROY, ANURADHA

| ART UNIT | PAPER NUMBER |
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3736

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,185

Applicant(s)

DONOFRIO ET AL.

Examiner

Anuradha Roy

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date July 12, 2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Regarding claim 9, Hickle discloses a conscious sedation system that includes a personalized message includes a command (Column 21, lines 23-26).

With reference to claim 10, Hickle discloses a conscious sedation system wherein the request is an audio stimulus (Column 21, lines, 37-41).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7, 8, 11, 12, & 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Hickle in view of Sobel (US Publication No. 20030216940).

Hickle discloses a conscious sedation system comprising: a) a controller (14) which generates an audio request for a predetermined response from a patient, the request including a personalized message; and b) a response testing apparatus including (256, 264, & 266): (1) a request assembly (256 & 264) which communicates to the patient the request generated by the controller; and (2) a response assembly (256 & 254) which detects the response and which communicates the response to the controller. However, Hickle does not disclose a conscious sedation system wherein the personalized message has a voice that the patient knows and presents information in a tone or accent most familiar to the patient, which includes the patient's name in the personalized message, and lastly can be revised manually or automatically. Furthermore, Hickle does not disclose an audio stimulus that is a sound or song that the

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-3, 5, 9, 10, & 14 rejected under 35 U.S.C. 102(b) as being anticipated by Hickle (US Patent No. 6,745,764).

Regarding claim 1, Hickle discloses a conscious sedation system comprising: a) a controller (14) which generates an audio request for a predetermined response from a patient, the request including a personalized message; and b) a response testing apparatus including (256, 264, & 266): (1) a request assembly (256 & 264) which communicates to the patient the request generated by the controller; and (2) a response assembly (256 & 254) which detects the response and which communicates the response to the controller.

In regards to claim 2 & 14, Hickle discloses a conscious sedation system, which includes a digital input to generate a personalized message (Column 11, lines 57-63). Examiner is contending that the personalized message is the specific information about the patient that the displayed on the display device directly from the inputs.

Regarding claim 3, Hickle discloses a conscious sedation system, which includes a keypad or touch screen (230 & 45) to input a patient's information.

With regards to claim 5, Hickle discloses a conscious sedation system, which includes a microphone (Column 17, lines 10-14) to enter the patient's information.

patient is familiar with. Sobel, however, teaches us the use of a personalized message capable of having a voice that the patient knows that presents information in a tone or accent most familiar to the patient [0036], which includes the patient's name (Figure 7, [0027]) in the message, and lastly can be revised manually or automatically ([0027], step 23). In addition to these elements, Sobel also discloses a system wherein the audio stimulus is a sound or song [0030] that the patient is familiar with. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include each of these elements to provide the patient with a greater level of comfort and familiarity during the medical procedure.

Additional Claim Rejections - 35 USC § 103


Claims 4, 6, & 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Hickie in view of Vatland (US Publication No. 20030212554).

As stated above, Hickie discloses a conscious sedation system comprising: a) a controller (14) and b) a response testing apparatus including (256, 264, & 266): (1) a request assembly (256 & 264); and (2) a response assembly (256 & 254). However, Hickie does not disclose a system that includes voice recognition software and text-to-speech software. However, Hickie does not disclose a system that incorporates a microphone to specifically input the voice or sounds that are used at least in part by the request assembly. Vatland, however, teaches of each of these elements. Vatland discloses a system for processing voice data that integrates voice recognition software ([0039] & Figure 8) and text-to-speech software (Abstract & [0025]). Additionally, Vatland discloses a system that incorporates a microphone [0039] to specifically input the voice or sounds that are used at least in part by the request assembly [0035]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to integrate a system to process voice recognition software, a text-to-speech software, and a microphone to facilitate the easy of use for the patient and doctor.

Conclusion

- [01] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bennett (US Patent No. 5,195,531) and Tsutsumi et al. (US Patent No. 6,315,736) disclose a system in determining a level of consciousness in a patient. Howell et al. (US Patent No. 6,215,992) discloses voice recognition software and text-speech software.
- [02] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anuradha Roy whose telephone number is (571) 272-6169 and whose email address is anuradha.roy@uspto.gov. The examiner can normally be reached between 8:00am and 4:00pm.
- [03] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726.
- [04] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~AR~


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